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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/800,839	03/07/2001	Toshihiro Shimizu	2535US1P	7614

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EXAMINER	
TRAN, SUSAN T	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 11/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/800,839	SHIMIZU ET AL.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 September 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-7,9-11 and 13-24* is/are pending in the application.

4a) Of the above claim(s) *22-24* is/are withdrawn from consideration.

5)☒ Claim(s) *10 and 11* is/are allowed.

6)☒ Claim(s) *1,2,4-7,9 and 13-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicant's Request for Extension of Time filed 09/06/05.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The 103(a) rejection over Lundberg alone has been withdrawn in view of applicant's Remarks.

The following 103(a) rejections are maintained:

Claims 1, 2, 4-7 and 13-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lundberg (US 6,132,770), in view of Watanabe et al. (Biol. Pharm. Bull. Vol. 18, No. 9).

Lundberg teaches an effervescent tablet comprising mixture proton pump inhibitor (ppi) core (acid-labile active substance) and filler, binder, lubricant, disintegrant, surfactant, other additives, and alkaline reacting agent (basic salt), including, calcium and magnesium salts (column 8, lines 55 through column 9, lines 1-5). Lundberg also teaches that the tablet having disintegrating time of about 55 seconds (see examples).

Lundberg is silent as to the teaching of the percent hydroxypropoxyl group, however, it is noted that Lundberg teaches a similar disintegration time using the

hydroxypropyl cellulose in his effervescent tablet (see examples). Accordingly, it is the position of the examiner that Lundberg teaches the use of at least similar hydroxypropyl cellulose having the claimed hydroxypropoxyl group. Therefore, the burden is shifted to applicant to present data showing that the hydroxypropyl cellulose taught by Lundberg is different in nature. Thus, it would have been obvious for one of ordinary skill in the art to, by routine experimentation determine a suitable hydroxypropyl cellulose to obtain the claimed invention, because Lundberg teaches the use of hydroxypropyl cellulose in an effervescent tablet (rapidly disintegrable solid dosage form) to achieve a desirable rapid disintegration time.

Lundberg does not expressly teach disintegrating the tablet in the mouth.

Watanabe teaches a rapid disintegrate compressed tablet comprising crystalline cellulose and low-substituted hydroxypropyl cellulose (L-HPC) (see page 1308, materials and methods section). The tablet which is rapidly disintegrated and dissolved in the mouth within 30 second, and having a crushing strength of 8-18 kgf (see page 1308, and page 1309, results and discussion section). Thus, it would have been obvious for one of ordinary skill in the art to prepare the effervescent tablet of Lundberg using crystalline cellulose and L-HPC in view of the teaching of Watanabe to obtain the claimed invention, because the references teach the advantageous results in the use of similar disintegrating agents for the same purpose, such as, Lundberg teaches the effervescent tablet is especially suitable for patients with swallowing disorders and in pediatrics (column 3, lines 53-55), and Watanabe teaches that it is necessary to develop a new type of tablet having the characteristics of rapid disintegration and

dissolution in saliva suitable for elderly patients, and patients having difficulties or experience inconvenience in swallowing (see page 1308).

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Makino et al. (US 5,501,861), in view of Watanabe et al. (Biol. Pharm. Bull. Vol. 18, No. 9).

Makino teaches a fast dissolving tablet comprising carbohydrate, and active agent including voglibose (see abstract; column 4, lines 42-43, 62-67; and column 5, lines 1-13). The composition further comprises other additives including disintegrators, binders, lubricants, and so on (column 5, lines 55-62).

Makino does not teach the use of low-substituted hydroxypropyl cellulose (L-HPC).

Watanabe teaches a rapid disintegrate compressed tablet comprising crystalline cellulose and low-substituted hydroxypropyl cellulose (L-HPC) (see page 1308, materials and methods section). The tablet which is rapidly disintegrated and dissolved in the mouth within 30 second, and having a crushing strength of 8-18 kgf (see page 1308, and page 1309, results and discussion section). Thus, it would have been obvious for one of ordinary skill in the art to prepare the fast dissolving tablet of Makino using crystalline cellulose and L-HPC as a disintegrator in view of the teaching of Watanabe to obtain the claimed invention, because the references teach the advantageous results in the use of similar disintegrating agents for the same purpose, such as, Makino teaches the fast dissolving tablet is suitable as a buccal dissoluble because of its easy solubility and disintegratability in the oral cavity (column 3, lines 9-

11), Makino also teaches the fast dissolving tablet having adequate compressed strength (column 3, lines 25-26), and Watanabe teaches a new type of tablet having the characteristics of rapid disintegration and dissolution in the mouth without the need of water, as well as excellent compressed strength (see pages 1308 and 1310).

Response to Arguments

Applicant's arguments filed 09/06/05 have been fully considered but they are not persuasive.

Applicant argues that the Examiner is still mistaken in thinking that since the cited reference teaches that an effervescing tablet has a disintegrating time of about 55 seconds, that the aspects of the invention presently claimed are obvious. In response to applicant's arguments, the Examiner fully understand applicants' remarks, however, upon reconsideration, the instant claims are obvious for the following reasons:

1) Although Lundberg does not expressly show the buccal dissolution time, applicant has not presented data showing that the tablet taught by Lundberg does not disintegrate in the mouth within the claimed time, since Lundberg does teach that the tablet having a disintegrating time of about 55 seconds in water (see examples). The Shimizu Declaration dated 10/14/04 does not, at all, show the disintegrating time in the mouth of the tablet taught by Lundberg. The Declaration only states the uncomfortable of large amount of carbon dioxide evolved if an effervescent tablet of Lundberg is taken orally without water. However, the result of discomfort is not a property that would aid in distinguishing over the teachings of Lundberg.

2) Although Lundberg does not expressly teach disintegrating the tablet in the mouth, however, nothing in Lundberg prevents or prohibits a patient to put the effervescent tablet taught in the mouth. Moreover, nothing in Lundberg would prevent a patient to put or chew the tablet and then using water or juice after chewing, or after the tablet has disintegrated in the mouth.

Applicants' reasons for not showing a side-by-side comparison have been fully consider but are not persuasive in view of the following reasons:

1) Inoperable due to engine failure is not a relevant analogy, because the Declaration does not show or declare that the effervescent taught by Lundberg is inoperable for oral administration. The Declaration only shows that large amount of CO_2 evolved would result in discomfort or uncomfortable (see page 4, second paragraph). However, nowhere in the Declaration states that the effervescent tablet of Lundberg is inoperable for oral administration.

2) The Declaration confirms that the effervescent tablet of Lundberg does disintegrate in the mouth.

3) It is noted that the Declaration requires the tablet to be held in the mouth for 1 minute. However, the dissolution time recites in the claims is from about 5 seconds to about 55 seconds. First, the Declaration does not show that the tablet of Lundberg does not disintegrate in the mouth within the claimed time. Second, the Declaration does not show that the tablet of Lundberg would result in discomfort if held in a mouth for a period of less than 1 minute.

4) Finally, as discussed above, nothing in Lundberg would prevent or prohibit one to chew or dissolve the tablet of Lundberg in the mount, and then drink water or juice if there is any discomfort. It is noted that the claimed invention does not preclude the use of water in concurrent with or after placing the tablet in the mouth.

In response to applicant's argument that Lundberg is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Lundberg teaches the effervescent tablet having disintegrating time in about 55 seconds using similar ingredients being claimed to obtain an oral tablet suitable in pharmaceutical art.

Applicant states that so far four Declarations have been submitted in the pending application, to try to show the Examiner the differences between cited art and the presently claimed invention. Despite applicant's every attempt to educate the Examiner, she continues to reject the present claims. However, in four of the Declarations submitted by the applicant, none of which show that the tablet of Lundberg does not disintegrate in the mouth within the claimed time.

Applicant argues that Watanabe does not cure the deficiencies of Lundberg. There is no teaching or suggestion in Watanabe of the use of L-HPC having 5% by weight or more to less than 7% by weight of hydroxypropoxyl group as is presently claimed in rejected independent claims 1 and 18-21. In response to applicant's

argument, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Lundberg teaches the effervescent tablet is especially suitable for patients with swallowing disorders and in pediatrics. Similarly, Watanabe teaches that it is necessary to develop a new type of tablet having the characteristics of rapid disintegration and dissolution in saliva suitable for elderly patients, and patients having difficulties or experience inconvenience in swallowing (see page 1308).

Applicant argues that neither Makino nor Watanabe disclose a solid preparation of the present invention including L-HPC having 5% by weight or more to less than 7% by weight of hydroxypropoxyl group. However, it is noted that although Watanabe is silent as to the claimed percentage of the hydroxypropoxyl group, Watanabe teaches the use of L-HPC that results in a quick dissolve tablet having the claimed disintegration time. There's no unexpected result being shown in the use of the particular hydroxypropoxyl group. Accordingly, it would have been obvious to one of ordinary skill in the art to, by routine experimentation determine a suitable percentage of the hydroxypropoxyl group to obtain the claimed invention, because Watanabe teaches a rapid disintegrate tablet, which disintegrates and dissolves in the mouth within 30 second, and because Watanabe teaches that it is necessary to develop a new type of tablet having the characteristics of rapid disintegration and dissolution in saliva suitable

for elderly patients, and patients having difficulties or experience inconvenience in swallowing (see page 1308).

Claims Allowable

Claims 10 and 11 are allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-R from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached at (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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